Data were also evaluated for patient responses to Herceptin® as a first line therapy (Table 5).

TABLE 5

FISH/Response with single agent Herceptin ® as 1st line therapy, 2+/3+ combined

	FISH+	FISH−
Response	17	1
No response	24	20
response rate	41% (26-56%)	20% (0-14%)

N = 62

The 41% response rate of FISH+ subjects was notably greater than the 27% response rate of 3+, 2+, subjects.

The surprising increase in likelihood of beneficial response based on FISH analysis extended to responses to chemotherapy plus Herceptin®, as shown in Table 6. FISH+ subjects showed a much greater response to chemotherapy and Herceptin® (54%) than FISH−(41%). Tables 7-9 contain more extensive data, broken down by different chemotherapeutic agents (adrinomycin and cyclophosphamide, AC; and Paditaxol, P) and different endpoints (response rate, time to progression, and survival) for Herceptin® in combination with chemotherapy.

TABLE 6

FISH/Response rate to chemotherapy +/− Herceptin ®, 1st line therapy; 2+/3+ combined

	C alone	C + H
FISH−	39% (26-52%)	41% (27-55%)
FISH+	27% (19-35%)	54% (45-63%)

N = 336

TABLE 7

Response rate of newly defined populations

		H + Ac (n = 143)	AC (n = 138)	H + P (n = 92)	P (n = 96)	H + CT (n = 235)	CT (n = 234)
2+/3+	469	56*	42	41*	17	50*	32
3+	349	60*	42	49*	17	56*	31
FISH+	240	58*	40	49*	14	54*	27

*p < 0.05

TABLE 8

Time to progression (months) of newly defined populations

		H + Ac (n = 143)	AC (n = 138)	H + P (n = 92)	P (n = 96)	H + CT (n = 235)	CT (n = 234)
2+/3+	469	7.8*	6.1	6.9*	2.7	7.4*	4.6
3+	349	8.1*	6.0	7.1*	3.0	7.8*	4.6
FISH+	240	7.8*	6.2	7.0*	3.2	7.3*	4.6

*p < 0.05

TABLE 9

Survival (months) of newly defined populations

		H + Ac (n = 143)	AC (n = 138)	H + P (n = 92)	P (n = 96)	H + CT (n = 235)	CT (n = 234)
2+/3+	469	27	21	22	18	25*	20
3+	349	31*	21	25	18	29*	20
FISH+	240	29*	20	25*	14	27*	18

*p < 0.05

These data uniformly confirm that FISH+ analysis, though correlating closely to IHC, provides a much more accurate indicator of likelihood of success with Herceptin® treatment. Across the board, FISH+ selection has about ⅓ (30%) greater response rate than 2+/3+ IHC-selection. When focused on 2+ patients, FISH status provides a much more effective tool for patient selection. FISH states also identifies patients who, because of 0 or 1+ status as determined by IHC, would otherwise be excluded from treatment.

These observations have broad implications for ErbB receptor antagonist-based cancer therapies and anti-tumor antigen cancer therapies in general. Thus erbB antagonists, e.g., anti-erbB receptor antibodies like Herceptin®, can have an increased likelihood of efficacy when administered to patients who are positive for erbB gene amplification, e.g., by a FISH test. This is certainly the case, based on these data, with Herceptin®.

The present invention is not to be limited in scope by the specific embodiments described herein. Indeed, various modifications of the invention in addition to those described herein will become apparent to those skilled in the art from the foregoing description and the accompanying figures. Such modifications are intended to fall within the scope of the appended claims.

It is further to be understood that all values are approximate, and are provided for description.

Patents, patent applications, publications, product descriptions, and protocols are cited throughout this application, the disclosures of which are incorporated herein by reference in their entireties for all purposes.

What is claimed:

1. A method for increasing likelihood of effectiveness of breast cancer treatment with humanized anti-ErbB2 antibody huMAb4D5-8, which method comprises administering a cancer treating dose of said antibody to a human subject diagnosed with breast cancer, wherein an erbB2 gene amplification in breast cancer cells in a tissue sample from the subject has been detected, and wherein the breast cancer cells from the human subject have been found to have a 0 or 1+ score of ErbB2 protein expression by immunohistochemistry.

2. The method according to claim **1**, wherein the breast cancer cells from the human subject have been found to have a 0 or 1+ score of ErbB2 protein expression by immunohistochemistry on a formaldehyde-fixed tissue sample.

3. The method according to claim **1** wherein the erbB2 gene amplification is detected by detecting fluorescence of a fluorescent-labeled nucleic acid probe hybridized to the gene.

4. The method according to claim **1**, which further comprises administering a cancer treating dose of a chemotherapeutic drug.

5. The method according to claim **4**, wherein the chemotherapeutic drug is a taxoid.

6. The method according to claim **1** wherein the likelihood of effectiveness increases by about 30%.

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